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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,444	01/04/2001	Esther H. Chang	2444-101	3962

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EXAMINER
NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
1632	8

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/601,444	Applicant(s) CHANG ET AL.	
	Examiner Dave Nguyen	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2000* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-70* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed actiion* .

Election/Restriction

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I. Claims 1-12, 29, 30, 38, 39, 49-50, drawn a liposomal complex comprising a virus, a cell-targeting ligand and a liposome, a first method of using the complex for providing a therapeutic agent to any cell.

Group II. Claims 13-28, 31-37, 40, 41-50, 63-70, drawn to a liposomal complex of less than 100 nm comprising a cell targeting ligand, a liposome and a therapeutic agent, the first method of providing the therapeutic agent to a target cell, and a method of making the liposomal complex of less than 100nm.

Group III. Claims 40, 41-50, drawn to a method of using a liposomal complex of less than 100 nm comprising a cell targeting ligand, a liposome and a therapeutic agent for delivering the agent to a cell of interest.

Group IV. Claims 63-70, drawn to a method of making a liposomal complex of less than 100 nm comprising a cell targeting ligand and a liposome.

Group V. Claims 51, 58-62, drawn to the second method of treatment of cancer by using a liposomal complex comprising a virus, a cancer cell-targeting ligand, a therapeutic nucleic aid molecule, and a liposome.

Group VI. Claims 52-62, drawn to the second method of treatment of cancer by using a liposomal complex comprising a cancer cell-targeting ligand, a therapeutic nucleic aid molecule, and a liposome, wherein the complex has a mean diameter of less than about 100 nm.

Group VII. Claims 13-17, 19-28, drawn to a third method of using a a liposomal complex comprising a cell-targeting ligand, a diagnostic agent, and a liposome, wherein the complex has a mean diameter of less than about 100 nm, for delivering the diagnostic agent to a cell.

The inventions are distinct, each from the other because of the following reasons:

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

37 CFR 1.475 (c) states

"If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present"

37 CFR 1.47 (d) also states:

"if multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17 (3) (a) and 1.476(c)".

In view of 37 CFR 1.475 (c) and 37 CFR 1.475 (d), Group I is considered the main invention that is drawn to a first product having a special technical feature of a liposomal complex comprising a virus, a cell-targeting ligand and a liposome and a first method using the liposomal complex, and a first method of for providing a therapeutic agent to any cell.

Groups II-VII are drawn to multiple distinct processes of use and/or multiple distinct products that do not share the same inventive concept as in Group I. The special technical feature of Invention II is a combination of a liposomal complex having a mean diameter of less than about 100 nm and a therapeutic agent. The special technical feature of each of invention III-VII is distinctly named method comprising materially distinct methods that would generate distinct function and effects. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I-VII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, it subject matter relates not to one but rather to three separate inventions not linked together by a common underlying inventive concept.

Should any of Groups I-III, and V-VII be elected, this application also contains claims directed to the following patentably distinct species of the claimed invention:

A/ A specifically named cell targeting ligand, *e.g.,* a tumor cell targeting ligand, folate, or transferrin.

Applicant is further required under 35 U.S.C. 121 and 372 to elect a single disclosed species of cell targeting ligand as listed above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the base claim of each invention is generic.

B/ A specifically named virus, *e.g.,* retrovirus or adenovirus.

Applicant is further required under 35 U.S.C. 121 and 372 to elect a single disclosed species of virus as listed above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the base claim of invention I is generic, for example.

C/ A specifically named agent intended for the delivery method or treatment method, *e.g.,* vector encoding antisense oligonucleotide or a protein.

Applicant is further required under 35 U.S.C. 121 and 372 to elect a single disclosed species of encoding vector as listed above for prosecution on the merits to which the claims shall be restricted if no

generic claim is finally held to be allowable. Currently, the base claim of each invention is generic.

D/ A specifically named mean diameter intended for the liposomal complex having a mean diameter of less than 100 nm, *e.g.,* of about 30 to 75 nm, or of about 50 nm.

Applicant is further required under 35 U.S.C. 121 and 372 to elect a single disclosed species of diameter as listed above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the base claim of invention II is generic, for example.

E/ A specifically named ratio between liposomes and nucleic acids, *e.g.,* 1.0-24 nanomole liposome per 1.0 ug nucleic acid, 6-16 nanomoles liposome per 1.0 ug nucleic acid, or 0.1-50 nanomoles liposomes per 1.0 ug nucleic acid.

Applicant is further required under 35 U.S.C. 121 and 372 to elect a single disclosed species of ratio as listed above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the claim 16 or 31 is generic, for example.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: None of the listed species as indicated above share a substantial common structure with respect to one another, thereby not constituting a special technical feature as defined by PCT Rule 13.2. Thus, the requirement of unity of the invention is not fulfilled.

Applicant is advised that a reply to this requirement must include an identification of the group and species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are

generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, and because it would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jacobs, whose telephone number is **(703) 305-3388.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051.**

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
Art Unit: 1632

DAVE T. NGUYEN
PRIMARY EXAMINER